



Measurement Challenges in Proteomics

Roadmapping America's Measurement Needs in the Protein Sciences

*March 12, 2006
Sheraton Boston Hotel
Boston, Massachusetts*



U.S. HUMAN PROTEOME
ORGANIZATION

Organizing Committee Charge to Participants

Executive Committee

Stanley Hefta, PhD
Bristol-Myers Squibb

William F. Koch, PhD
National Institute of Standards and Technology

John Kozarich, PhD
ActivX Biosciences

Joshua LaBaer, MD, PhD
Harvard Institute of Proteomics

James R. (Rick) Ludwig, PhD
INCAPS

Gilbert S. Omenn, MD, PhD
University of Michigan

Henry Rodriguez, PhD, MBA
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Sudhir Srivastava, PhD
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The word “proteome” is derived from PROTEins expressed by a genOME, and it refers to all the proteins produced by an organism, much like the genome is the entire set of genes. The human body contains a vast number of different proteins, each having different functions. As the main components of the physiological pathways of the cells, proteins serve vital functions in the body. Proteomics plays an important role in drug discovery, diagnostics and molecular medicine, providing a link between genes, proteins, metabolites, and disease.

The National Institute of Standards and Technology (NIST) is facilitating a U.S. MEASUREMENT SYSTEM (USMS) INITIATIVE that will be undertaken in close cooperation with the private and public sectors to ensure that the nation’s highest-priority measurement needs are identified and met in the 21st century. NIST plans to publish a USMS Roadmap on a regular basis, reporting to USMS customers and stakeholders on what should be done, by NIST and others, to meet the needs of the USMS, and delineating the consequences of not meeting those needs. The *Measurement Challenges in Proteomics* Workshop is part of this initiative and will endeavor to survey (identify and prioritize) system-wide needs in coordinating, performing and using protein measurements.

The inability to establish performance criteria to better understand the quality of proteomic technique results, has led to poor confidence in protein measurement techniques, difficulty in assessing the agreement of different experiments, conflicting reports in the literature, and lost opportunities. If proteomics technologies are to successfully make their way into clinical diagnostics, universally accepted metrics will be needed at many steps along the way to help clarify experimental results and protocols and make them comparable.

By participating in this workshop, members will help identify and prioritize a measurement needs agenda that addresses the technical infrastructure (measurement science, standards, and data) in the field of proteomics. Participants will also identify how best to transfer knowledge and share priorities across industry, clinical laboratories, government, funding agencies, regulatory agencies, educational and not-for-profit institutions in order to build strong collaborations and partnerships. By the end of the workshop, a roadmap of the measurement needs should be outlined. The steps needed to address these needs as well as the consequences of inaction will be stated.



National Institute of Standards and Technology
U.S. Department of Commerce
U.S. Human Proteome Organization

Measurement Challenges in Proteomics Workshop

March 12, 2006

Boston Sheraton Hotel
Boston, MA

AGENDA

- | | |
|-------------------|---|
| 7:00 AM – 7:45 AM | Registration and Continental Breakfast |
| 7:50 AM – 8:00 AM | Welcome and Introduction

<i>Henry Rodriguez, PhD, MBA</i>
<i>National Institute of Standards and Technology</i>

<i>Thomas Wiggins BSME, MBA</i>
<i>National Institute of Standards and Technology</i> |
| 8:00 AM – 8:10 AM | NIST and the Science of Measurement

<i>Willie E. May, PhD</i>
<i>National Institute of Standards and Technology</i> |
| 8:10 AM – 8:20 AM | US Measurement System Initiative

<i>Dennis Swyt, PhD</i>
<i>National Institute of Standards and Technology</i> |
| 8:20 AM – 8:40 AM | A Need for Measurement Standards in Proteomics
(HUPO PPP and NCI EDRN)

<i>Gilbert S. Omenn, MD, PhD</i>
<i>University of Michigan</i>

<i>Sudhir Srivastava, PhD</i>
<i>National Cancer Institute</i> |
| 8:40 AM – 9:00 AM | Steps & Complexities Involved In Measuring Proteins/Peptides

<i>Daniel W. Chan, PhD</i>
<i>Johns Hopkins Medical Institutions</i> |

9:15 AM – 3:30 PM **BREAKOUT SESSIONS**

SESSION 1

SAMPLE PREPARATION AND PROTEIN SEPARATION

Successful protein separation is mainly dependent upon decisions made regarding sample preparation. Identifying the pros and cons of common and emerging methodologies and technologies used in sample preparation (collection, processing and storage) and protein separation is the first step in achieving results that are accurate and reproducible.

Lead Moderator: *Andrew Link, PhD*
Vanderbilt Medical Center

Co-Moderators: *Gilbert S. Omenn, MD, PhD*
University of Michigan
Thomas Wiggins BSME, MBA
National Institute of Standards and Technology

Facilitator: *Herbert F. Barber*
National Institute of Standards and Technology

SESSION 2

PROTEIN IDENTIFICATION AND QUANTIFICATION

A high degree of confidence in the identification and quantification of proteins and their posttranslational modifications - in complete expression profiles or in the context of defined protein complexes – remains a challenge to proteomics research and a concern to regulatory agencies and the industrial community. A key requirement for this approach is the ability to resolve the individual components of complex protein and peptide mixtures with a high level of confidence across multiple platforms. Criteria to be assessed include sensitivity and selectivity, reproducibility and robustness, and suitability for compliance with current guidelines. This session will address the technical issues encountered in protein identification and quantification.

Lead Moderator: *David R. Goodlett, PhD*
University of Washington

Co-Moderators: *Stanley Hefta, PhD*
Bristol-Myers Squibb
David Bunk, PhD
National Institute of Standards and Technology

Facilitator: *Mike Martin*
National Institute of Standards and Technology

SESSION 3
PROTEOMIC ASSAY DEVELOPMENT AND
VALIDATION (MULTIPLEX/FUNCTIONAL/HIGH
THROUGHPUT)

Proteomic biomarkers need to be validated (analytically and biologically) and developed into robust assays. Given the chemical and structural complexity of the proteome, the development of proteomic high throughput assays has been challenging. Validation of an analytical method identifies the sources of potential error and quantifies the performance characteristics of an assay. Validation of the technology/method will ensure that it provides reliable information for the intended diagnostic application, and therefore is a key component of the development and approval process. Addressing the issues encountered in multiplex and functional proteomic assay development and validation will help provide guidance for the selection of analytical techniques and their optimal use.

Lead Moderator: *Joshua LaBaer, MD, PhD*
Harvard Institute of Proteomics

Co-Moderators: *John Kozarich, PhD*
ActivX Biosciences
Henry Rodriguez, PhD, MBA
National Institute of Standards and Technology

Facilitator: *Rick Ludwig, PhD*
INCAPS

SESSION 4
STUDY DESIGN AND EXPERIMENTAL DESIGN

Proper study design and experimental design is a requisite for clinical proteomics. However, a lack of uniformity and standards in data collection, data interpretation, and inadequate sample size with associated demographic and clinical information has led to irreproducibility of data, uncertainties, and bias-rich results. This session will address the variables that affect confounding and bias results and ways to minimize them.

Lead Moderator: *Jane C. Schroeder, DVM, PhD*
University of North Carolina School of Public Health

Co-Moderators: *Sudhir Srivastava, PhD*
National Cancer Institute
Paul Wagner, PhD
National Cancer Institute

Facilitator: *William F. Koch, PhD*
National Institute of Standards and Technology

For each session:

9:15 AM - 10:20 AM **Identifying the Issues/Needs in Proteomics**

10:20 AM - 10:40 AM **Coffee Break**

10:45 AM – 11:50 AM **Clarifying, Refining and Combining the Issues/Needs**

Noon – 1:15 PM **Lunch**

1:20 PM – 3:30 PM - **Prioritize the Issues/Needs in Order of Importance**
- **Recommend Approaches to Solve**

3:30 PM – 3:50 PM **Soda Break**

4:00 PM – 6:00 PM **Outcomes/Recommendations presented to workshop attendees**

6:00 PM **Adjourn**



March 12, 2006

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Questions? Call

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Online Registration

<http://usms.nist.gov/workshops/proteomic.htm>

**Workshop registration along with breakout session
preferences are done online**

Breakout Session Selection

Pre-registration is required. Due to the number of sessions and attendees, seating will be limited. Selections will be made on a "first come, first serve" basis; so register early.

Registration Fee: \$125

Hotel Information

Sheraton Boston Hotel
Prudential Center
39 Dalton Street
Boston, Massachusetts USA 02199
Phone (617) 236-2000 Fax (617) 236-1702

Nestled in charming and historic Back Bay, the Sheraton Boston Hotel is conveniently located from Boston's Logan Airport, connected to the Hynes Convention Center and to 200 shops at the Prudential Center and Copley Place Mall.

Registrants are encouraged to reserve their rooms by contacting the hotel directly. When booking your stay make sure to mention that you will be attending the Measurement Challenges in Proteomics workshop. A number of rooms have been reserved at a rate of \$189/night + tax.